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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,803	12/02/2003	Thomas J. Maginot	22220-08626	4106

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FENWICK & WEST LLP
SILICON VALLEY CENTER
801 CALIFORNIA STREET
MOUNTAIN VIEW, CA 94041

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,803

Applicant(s)

MAGINOT, THOMAS J.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/01/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Terminal Disclaimer

The terminal disclaimer does not comply with 37 CFR 1.321(b) and/or (c) because:

An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

In addition, the owner Origin Medsystems, Inc. is not of record as being the owner of the present application.

Double Patenting

Claims 7 and 9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/731,068 in view of Redtenbacher (US 4,817,847). Although the conflicting claims are not identical, they are not patentably distinct from each other because copending claim 1 is broader than present claim 7 except for the endoscope used therein. However, Redtenbacher teaches that the use of endoscope in similar methods was known. Therefore, it is the Examiner's position that it would have been obvious to use an endoscope in the method of claim 7 for the same reasons that Redtenbacher uses the same and in order to allow better viewing of the operation site.

With regard to claim 9, claim 1 is read on or anticipated by claim 9 alone. For this reason, these two claims are considered clearly obvious in view of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-6 of U.S. Patent No. 6,401,721.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are broader in scope as compared to the patented claims but are read on by the patented claims. For this reason, the present claims are considered to be clearly obvious in view thereof.

Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No.

5,749,375. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are broader in scope as compared to the patented claims but are read on by the patented claims. For this reason, the present claims are considered to be clearly obvious in view thereof.

Claims 11, 12, and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 12, and 15 of U.S. Patent No. 5,571,167. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are broader in scope as compared to the patented claims but are read on by the patented claims. For this reason, the present claims are considered to be clearly obvious in view thereof.

Specification

Upon further review of the specification and the amendments made thereto, it was noticed that the amendment to the specification on August 26, 2004 to add 09/475,789 to the continuing data was after 4 months from the filing date of the present application and after 16 months from the filing date of the parent application. For this reason, the provisions of 37 CFR 1.78 (a) (2) (i) have not been complied with. Since there was not copendency between the parent application and 09/111,062, the effective filing date of the present claims is July 11, 2001.

If applicant desires benefit of a previously filed application under 35 U.S.C. 120, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has

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become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5)

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and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Maginot (US 5,456,712). Maginot anticipates the claim language because it has an identical disclosure to the present one and the effective filing date of the present claims is July 11, 2001 as explained earlier. Since the change to the continuing data was not made with a granted petition, it is not proper and does not have the effect of reestablishing the earlier effective filing dates.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Barone et al (US 5,360,443). Barone anticipates the claim language where the selected site is the aortic aneurysm site (see Figures 1-4). The advancing end portion is shown in Figure 5 (prior to advance to Figure 1 (after advance) of tube (160) through sheath (186). The anastomosis is formed between the aorta and the graft because "an operative union of two hollow or tubular structures" is made (Stedman's Medical Dictionary, 23rd Edition

(1976) page 65). The end portion is adjacent the aorta even though it is within it because it is adjacent the aortic wall.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brewster (article entitled "Direct Reconstruction for Aortoiliac Occlusive Disease") in view of Ablaza (US 4,190,909). Brewster teaches side-to-end anastomosis of arteries with a blood-conveying conduit, but fails to teach doing so under substantially intact skin; see pages 674 to 676. However, Ablaza teaches that it was known to keep skin substantially intact because Ablaza keeps the skin substantially intact by using only an incision where the connection point is under completely intact skin. The terminology "substantially" of "substantially intact" is being treated as a broad term, which encompasses skin that has been cleanly incised with a scalpel, for example. Therefore, it is the Examiner's position that it would have been prima facie obvious to implant the Brewster graft under "substantially intact skin" so that bleeding and trauma to the skin could be reduced and so that a clean barely visible scar would result upon healing.

With regard to claim 5, one of the anastomotic connections are made below the inguinal ligament which is clearly shown in the figures; see Figures 55-6 D and 55-7.

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Claim 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster (US 5,366,819) in view of Loiterman (US 4,983,165). Kaster discloses a medical procedure for connecting a blood vessel and blood conveying conduit extravascularly, but fails to disclose the use of a visualization device or endoscope as claimed.

However, Loiterman teaches that it was known to the art at the time the invention was made to use visualization devices and endoscopes with catheters; see column 1, lines 13-21. Therefore, it is the Examiner's position that it would have been prima facie obvious to use a visualization device or endoscope with the Kaster method so that the progress of the operation could be more fully monitored making it safer and more efficacious.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster (US 5,366,819) in view of Ruppert (US 5,129,913). Kaster meets the claim language where the advancing step is disclosed on column 11, lines 37-43, and the instrument as claimed is the hole punch of Kaster the forms hole for the anastomosis (see column 11, line 37 to column 12, line 38). It is noted that the order of the steps are not required to be the same as they are listed in the claim.

Kaster fails to disclose the features of the hole punch. However, Ruppert teaches that hole punches of the art with lumens (sleeve (11)) having a surgical device (rod (20)) were known; see the drawings and column 2, line 30 to column 3, line 11. Therefore, it is the Examiner's position that it would have been obvious to use the hole punch of Ruppert as the hole punch of Kaster to make a clean punch hole where longevity of the blade is desired; see the abstract of Ruppert.

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Response to Arguments

Applicant's arguments filed October 5, 2004 have been fully considered but they are not persuasive.

In response to the traversal of the Brewster in view of Ablaza rejection that there is no entry point below the inguinal ligament, the Examiner directs Applicant see the figures on pages 675 and 676 where one of the anastomotic connections is made below the inguinal ligament that is shown in the drawings; see Figures 55-6 D and 55-7.

The remaining rejections have been changed to the extent that Applicant's arguments are not longer relevant thereto.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish at the end.

Paul Prebilic
Primary Examiner
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